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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,473 04/24/00 HAMLIN

IM22/0515

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EXAMINER	

ABT/UNITR	PAPER NUMBER
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DATE MAILED:

05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/557,473	Applicant(s) HAMLIN, ROBERT N.	
	Examiner Rena L. Dye	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 March 2001.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 20) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Claim Rejections - 35 USC 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 26,28-32 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdrahala (5,248,305).

Zdrahala teaches an extruded catheter and *other flexible plastic tubing* manufactured from a liquid crystal polymer (LCP) (Figure 3; column 2, lines 13-28). The extruded LCP material may be coated, by coextrusion or subsequent extrusion, with a layer of typically non-liquid crystal polymer formulation which has tissue compatible characteristics. Also or alternatively, the coating may be on the inner surface of the tube of liquid crystal polymer material (column 2, lines 28-39). The coating may be a smooth, hemocompatible surface plastic material which may have lubricating characteristics. Coating materials are listed at column 4, lines 34-50 and are different materials than that of the LCP. Tubes extruded in accordance with this invention for catheters or any other use may be biaxially oriented in that they may be longitudinally stretched, simultaneously with the rotation of the extrusion die (column 4, lines 55-61).

\*Zdrahala further teaches that the tubular catheter body may then have applied to it the customary parts, connections and the like used in the manufacture of conventional catheters of

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every type (column 4, lines 51-54). Although Zdrahala fails to expressly teach a balloon, it is the Examiner's position that a balloon configured to be attached to a catheter would be included in the teaching of "other flexible plastic tubing" as well as "customary parts, connections and the like." Therefore, it would have been obvious to one having ordinary skill in the art to have made a balloon from LCP as taught by Zdrahala which would meet the limitation of "other flexible plastic tubing", or to have provided a balloon made of LCP to be used in combination with the catheter made of LCP. Since Zdrahala teaches that the LCP is tissue compatible it would have been obvious to one having ordinary skill in the art to have made the customary parts, connections and the like, *or an inflatable balloon*, from the LCP.

Although Zdrahala does not expressly teach the second layer as an adhesion layer, again Zdrahala teaches that the extruded catheter body may then have applied to it the customary parts, connections and the like used in the manufacture of conventional catheters of every type (column 4, lines 51-54). Therefore, it would have been obvious to one having ordinary skill in the art to have provided the inner layer with a polymer having adhesive properties so that the catheter could be connected to other parts.

### ***Double Patenting***

3. Claims 26-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,270,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '086. The comprising language recited in independent claim 26 is broad

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enough to include the recited outer tensile layer and inner bonding layer of '086. Furthermore, '086 defines the outer tensile layer as including LCP (column 2, lines 31-42).

4. Claims 26-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-50 of copending Application No. 08/907,170. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '170. The comprising language recited in independent claim 26 is broad enough to include the recited first layer of a biaxially oriented polymer (polyester) and a second layer or a biaxially oriented polymer (polyolefin).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Allowable Subject Matter*

5. Claims 27 and 33 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and if Applicant files terminal disclaimers to overcome the obviousness type double patenting rejections.

The prior art of record fails to teach or suggest a medical balloon catheter comprising an inflatable expandable balloon configured to be attached to a catheter, the balloon comprising liquid crystal polymer (LCP) wherein the balloon has a radial expansion not exceeding 3-10 percent when inflated to seven atmospheres.

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6. Applicant's arguments filed on March 1, 2001 have been fully considered but they are not persuasive.

Applicant's arguments regarding the Zdrahala reference have been addressed in the rejection above. It is the Examiner's position that Zdrahala would include the teaching of "an inflatable expandable balloon" as recited in the present claims since Zdrahala specifically teaches "other flexible plastic tubing" as well as "customary parts, connections and the like."

The Examiner has noted that Applicant acknowledges the obviousness-type double patenting rejections over claims in U.S. 5270086 and U.S. Patent Application No. 08/907,170 (allowed), and intends to file an appropriate terminal disclaimer upon the indication of allowable subject matter.

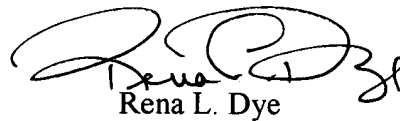
#### *Conclusion*

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Dye whose telephone number is (703) 308-4331.

A handwritten signature in black ink, appearing to read 'Rena L. Dye', with a stylized flourish at the end.

Rena L. Dye  
Primary Examiner  
Tech Center 1700

R. Dye  
May 14, 2001